

PATENT

Attorney Docket No. 0803-0111.03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)	Examiner: Elizabeth A.
Dilip K. Nakhasi)	Gwartney
Roger L. Daniels)	
)	Group Art Unit: 1781
For:)	
HEALTH AND NUTRITION PROMOTING)		Confirmation No. 1259
CHARACTERISTICS, CONTAINING)	
INTERESTERIFIED LIPIDS AND)	
PHYTOSTEROL, AND RELATED)	
METHODS)	
)	
Filed: August 21, 2006)	
)	
Serial No.: 10/598,215)	

DECLARATION OF KARL A. SCHEIDT UNDER RULE 132

I, Karl A. Scheidt, do hereby declare as follows:

1. I am a Professor of Chemistry at Northwestern University in Evanston, Illinois and have no affiliation or connection with the proprietor of the above-captioned patent application.

2. I hold the following academic degrees:

Bachelor's degree in Science (BSc) from the University of Notre Dame in South Bend, Indiana (1994) and a Ph.D. in Chemistry from Indiana University in Bloomington, Indiana (awarded 1999).

3. I am a principal of the Scheidt Research Group at Northwestern University in Evanston, Illinois, and have

substantial academic training and extensive experience in organic chemistry, including a full working knowledge of interesterification, both academically and experientially. I am an expert in chemical synthesis, catalysis, natural products and medicinal chemistry, and I hold a research professor chair and a teaching chair of excellence from Northwestern University.

4. I have been informed that certain claims of the above-captioned application have been rejected as being unpatentable from Aoyama U.S. Patent No. 6,827,963 of The Nisshin Oillio, Ltd. ("Aoyama") as the primary reference.

5. I have studied Aoyama as well as the above-captioned application (in the form of Patent Application Publication No. 2007/0141221). I also have considered the Office Action dated March 31, 2010 and particularly the arguments in that Office Action in support of the rejection of the application claims in reliance on Aoyama combined with other references, namely Wester that concerns the incorporation of phytosterol esters into foods and the St.-Onge et al. publication regarding dose levels for lowering cholesterol. My present Declaration is directed only to Aoyama and to interesterification chemistry.

6. I am aware that this Declaration is offered in support of the patentability of the claims of the above-captioned patent application and that these claims call for, *inter alia*, a structured lipid component having randomly interexchanged fatty acid chains that vary from glycerol structure to glycerol structure. At times I refer to these randomly interesterified components using the term in the above-captioned patent application of "structured lipid".

7. I have particularly directed my attention to the following passages in this Office Action:

While Aoyama discloses directed interesterification to prepare the triglycerides of Example 1 and 3, the reference also discloses the use of chemical, i.e. random, interesterification (C8/L18-23). Given Aoyama discloses triglycerides prepared by random interesterification, intrinsically the structured lipid component would have randomly interexchanged said first fatty acid chains and said second fatty acid chains that vary randomly from glycerol structure to glycerol structure.
(pp. 4-5 and 8, Office Action)

* * *

It is noted that applicants define randomization as a chemical reaction whereby individual fatty acid structures at positions of the triglyceride being interesterified are

interchanged on the glycerol moiety ([0010]). Similarly, Aoyama discloses chemical interesterification (C8/L18-23). Therefore, it is the Examiner's position, given Aoyama discloses a chemical interesterification method substantially similar to randomization described by applicant, that Aoyama discloses a triacylglycerol structure which has interchanged fatty acid moieties that vary from glycerol structure to glycerol structure. (p. 11, Office Action)

I fully understand that column 8 of Aoyama states that the fats and oils composition according to the Aoyama invention "may be prepared by means of" a variety of methods, one of which is "a chemical synthesis method." I further observe this is the one and only time Aoyama mentions or provides any information concerning "a chemical synthesis method". Based on my expertise in the chemistry of interesterification, I disagree that this mention of "chemical synthesis" in the context of the rest of Aoyama means, as stated in the passage quoted above, that "intrinsically the structured lipid component would have randomly interexchanged said first fatty acid chains and said second fatty acid chains that vary randomly from glycerol structure to glycerol structure". Also based on my expertise in the chemistry of interesterification, I disagree that "Aoyama discloses a chemical

interesterification method substantially similar to randomization described by applicant". The following explains why I so disagree.

8. In addition to "chemical synthesis" that passage in column 8 of Aoyama also states the Aoyama fats and oils "may be prepared by means of, but not to be limited to, an enzyme method . . . a method of extracting from natural fats and oils, and a genetic recombination method of oil seeds." Of these four briefly listed methods, Aoyama provides details only for the enzyme method. Aoyama provides no guidance to one of ordinary skill in the esterification art about using any method (besides the enzyme method) to make the fats and oils composition of Aoyama.

9. In order for one of ordinary skill in esterification to use "a chemical synthesis method" to drive the esterification toward the Aoyama compositions, which Aoyama says are triglycerides of specific structures or Formulas (namely Formula I, Formula II, Formula II', Formula III, Formula III', Formula IV, Formula V, and Formula VI), much more information would be required than the short phrase "a chemical synthesis method". It is possible that Aoyama provides adequate information to

enable one of ordinary esterification skill to drive an esterification toward these Formulas by using the enzyme method disclosed in some detail in Aoyama. This is not the case for any of the other three methods listed in column 8 of Aoyama.

10. It is undeniable that Aoyama does not disclose the interesterified structured lipid commensurate with the claims of the above-captioned patent application. Instead, Aoyama discloses triglycerides of the Formulas.

11. In addition, the entirety of Aoyama is not even remotely adequate to prepare the invention of the above-captioned patent application, namely a structured lipid that is an interesterified randomization product with fatty acid moiety chains from one glycerol exchanged with fatty acid moiety chains from another, different glycerol, the structured lipid having randomly interexchanged different fatty acid moiety chains that vary from glycerol structure to glycerol structure.

12. Aoyama does not teach or enable the skilled esterification artisan about randomly interexchanged structured lipids or to a method of making them so as to be commensurate in scope with the claims of the above-captioned patent application. As observed in paragraph 9

above, Aoyama states that the Aoyama fats and oils composition of the Formulas may be prepared by "a chemical synthesis method." While I question if it is even possible to make the fats and oils composition described in the Aoyama patent by "a chemical synthesis method", it is much more certain that a full and thorough reading of Aoyama would not enable the ordinarily skilled artisan to carry out "a chemical synthesis method" that prepares the randomly interexchanged structured lipids specified in the claims of the above-captioned patent application.

13. The arguments in the Office Action quoted in paragraph 7 above fail to recognize that the Aoyama statement of esterification by "a chemical synthesis method" does not mean applicant's structured lipids intrinsically are prepared by random interesterification, even if there may be identity of reactants. Since enzymes and chemical catalysts are very different from each other (for example, the former has a relatively complex large chemical structure and the latter is of a relatively small and simple chemical structure), each react with substrates at different rates and with different selectivities based on many characteristics including, but not limited to, shape, size and electrostatic interactions, then enzymatic

methods clearly will generate interesterification products different from interesterification products generated by chemical synthesis methods. In this case, MCTs and long chain lipids will directly interact with the large relative structure of enzyme from the enzymatic method while small organic molecules from the "chemical synthesis method" are much smaller and would not have this type of enzyme-lipid interaction. To illustrate further, without being told anything by Aoyama about interesterification conditions when following "a chemical synthesis method", the skilled artisan cannot determine what ester chemical structures would be produced from those reactants. Chemical synthesis conditions that are basic (e.g. methoxide) produce a different chemical distribution of esters compared to chemical synthesis conditions that are acidic.

14. As a further example of characteristics influencing chemical synthesis in this context, interesterification conditions are illustrated in the above-captioned patent application. Such includes paragraphs [0035] through [0039], as well as the working Examples of the above-captioned application, including information provided in paragraph [0055]. The above-captioned patent application also provides physical

properties concerning the products made through the use of the interesterification catalyst for driving interesterification to or toward complete randomization. Such properties are described, for example, in paragraphs [0058]-[0060] and [0083]-[0095].

15. Facts and information referred to in the preceding paragraphs direct me to conclude that the skilled esterification artisan would appreciate, upon reading and understanding the Aoyama patent, that Aoyama says "a chemical synthesis method" could be used to prepare the fats and oils compositions of the Aoyama Formulas. However, the skilled esterification artisan is not taught or enabled by Aoyama how even one such Formula fats and oils composition is made by "a chemical synthesis method".

16. Facts and information in the preceding paragraphs direct me to conclude that the skilled esterification artisan would be taught by Aoyama that "a chemical synthesis method" would not drive interesterification to or toward randomization as specified in the claims of the above-captioned patent application. Instead, the skilled esterification artisan would be taught that "a chemical synthesis method" results in esterification driven toward the Formulas fats and oils of Aoyama.

17. Facts and information in the preceding paragraphs, along with my expertise in connection with esterification, direct me to conclude that the interesterification artisan would not be enabled to achieve random interexchanging through interesterification by the simple statement in Aoyama of "a chemical synthesis method." Conditions such as those provided in the above-captioned patent application are absolutely essential.

18. I hereby declare that all statements made herein and of my knowledge are true and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Dated: July 20, 2010


Karl A. Scheidt